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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,155	03/01/2004	Arnon Lavie	02-134-D	3822

7590 02/28/2006

Jason J. Derry
McDonnell Boehnen Hulbert & Berghoff LLP
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Chicago, IL 60606

EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,155	LAVIE ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-169* is/are pending in the application.

4a) Of the above claim(s) *3, 9-10, 13-68 and 70-169* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8,11,12 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/10/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Exhibit A

DETAILED ACTION

The Amendment filed on 1/3//06 in response to the previous Non-Final Office Action (9/26/05) is acknowledged and has been entered.

Claim 2 has been cancelled. Claims 3, 9-10, 13-68 and 70-169 have been withdrawn for non-elected invention. Claim 11 has been amended. Claims 1 and 3-169 are pending. Claims 1, 4-8, 11-12, and 69 are under consideration.

Information Disclosure Statement

The information disclosure statement (s) (IDS) submitted on 1/10/06 are/is considered by the examiner and initialed copy of the PTO-1449 is enclosed.

Response to Arguments

Rejection under 35 USC § 103

1. The rejection of Claims 1, 4-5, 11-12 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagshawe et al., (US Patent, 6299876, 2001) in view of Wolfgang et al., (WO 0188106, Nov, 2001) is maintained for the reasons of record in the prior Office Action (9/26/05, page 2-3) and made again for the newly amended claim 11.

The response filed 1/3/06 has been carefully considered but is deemed not to be persuasive. The response states that Bagshawe et al., don't teach improving the activation of a cytotoxic agent and don't teach modified deoxycytidine kinase. The response also states that Knecht et al., (wrongly spelled as "Wolfgang" of WO 01/88106 by in prior Office action, the office apologizes for the oversight) only disclose the effect of deoxyribonucleoside kinase variants, and not deoxycytidine kinase (dCK) and its effect. In response this argument, the primary reference by Bagshawe et al., teach a conjugate, which contains an antibody recognizing a cell surface antigen on a tumor cell and an enzyme, which could increases the cytotoxicity of the chemotherapeutic drug. As stated in prior Office Action, the reference by Knecht et al., teaches human deoxycytidine kinase (dCK), a family member of deoxyribonucleoside kinase, evidenced by NCBI MeSH word search (exhibit A) as well as modified dCK having nucleotide mutation as SEQ ID NO: 5 of instant claims (see sequence search provided in prior Office action

9/26/05), Knecht et al., also teach that the modified enzyme increases enzymatic activity towards nucleoside analogs, further that the enzyme promotes the conversion of prodrug into a cytotoxic drug (page 4, line 17-20 and table 1, page 8, sequence alignment), which would comprise any chemotherapeutic agent. In addition, since dCK of Knecht et al., has the same amino acid sequence, which would be expected to have same activity as claimed deoxycytidine kinase.

2. The rejection of 1, 4-8 and 11-12 under 35 U.S.C. 103(a) as being unpatentable over Bagshawe et al., (US Patent, 6299876, 2001) and Knecht al., (WO 0188106, Nov, 2001) and further in view of Kossman et al., (Clin Can Res. Vol. 5, Page 2748-55, 1999) is maintained for the reasons of record in the prior Office Action (9/26/05, page 2-3) and made again for the newly amended claim 11.

Kossman et al., teach HuM195 antibody, which recognize CD33 antigen expressed on the myeloid leukemia cells.

As discussed above, Bagshawe et al., teach an antibody-enzyme conjugate, Kchecht et al., teach enzymes, dCK and modified dCK, which could convert a prodrug to cytotoxic drug, and Kossman et al., teach HuM195 antibody, which could recongnize CD33 on the tumor cells. It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to make enzyme-antibody conjugate using dCK or modified dCK and HuM195 antibody with the expected benefit of each agent for a cancer treatment. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to combine the teachings of all three references to make and use the conjugate with better result for the cancer therapy.

Conclusion

NO claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-

MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

SHEELA HUFF
PRIMARY EXAMINER

Exhibit A

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☐ **1: Deoxycytidine** Lin

Year introduced: 1975(1973)

Subheadings: This list includes those paired at least once with this heading ir MEDLINE and may not reflect current rules for allowable combinations.

☐ administration and dosage ☐ adverse effects ☐ analogs and derivatives
☐ analysis ☐ antagonists and inhibitors ☐ biosynthesis ☐ blood
☐ cerebrospinal fluid ☐ chemical synthesis ☐ chemistry
☐ contraindications ☐ diagnostic use ☐ economics ☐ genetics
☐ immunology ☐ isolation and purification ☐ metabolism
☐ pharmacokinetics ☐ pharmacology ☐ physiology ☐ radiation effects
☐ secretion ☐ standards ☐ therapeutic use ☐ toxicity ☐ urine

☐ Restrict Search to Major Topic headings only
☐ Do Not Explode this term (i.e., do not include MeSH terms found below this term in the MeSH tree).

Registry Number: 951-77-9

Entry Terms:
- CDR
- Cytosine Deoxyribonucleoside
- Deoxyribonucleoside, Cytosine
- Cytosine Deoxyriboside
- Deoxyriboside, Cytosine

Previous Indexing:
- Nucleosides (1966-1972)

All MeSH Categories

Chemicals and Drugs Category
Nucleic Acids, Nucleotides, and Nucleosides
Nucleosides
Deoxyribonucleosides
Deoxycytidine
Bromodeoxycytidine
Zalcitabine
Lamivudine

All MeSH Categories
Chemicals and Drugs Category
Nucleic Acids, Nucleotides, and Nucleosides
Nucleosides
Pyrimidine Nucleosides
Cytidine
Deoxycytidine
Bromodeoxycytidine
Zalcitabine
Lamivudine

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- Select PubMed under the Links menu to retrieve all records for the MeSH Term.
- Select NLM MeSH Browser under the Links menu for additional informatio

☐ **1: Deoxyribonucleosides** Lin

A purine or pyrimidine base bonded to DEOXYRIBOSE.
Year introduced: 1973

Subheadings: This list includes those paired at least once with this heading ir MEDLINE and may not reflect current rules for allowable combinations.

☐ administration and dosage ☐ adverse effects ☐ analogs and derivatives
☐ analysis ☐ antagonists and inhibitors ☐ biosynthesis ☐ blood
☐ cerebrospinal fluid ☐ chemical synthesis ☐ chemistry ☐ genetics
☐ immunology ☐ isolation and purification ☐ metabolism
☐ pharmacokinetics ☐ pharmacology ☐ physiology ☐ radiation effects
☐ therapeutic use ☐ toxicity ☐ urine

☐ Restrict Search to Major Topic headings only
☐ Do Not Explode this term (i.e., do not include MeSH terms found below this term in the MeSH tree).

Previous Indexing:
- Nucleosides (1966-1972)
- specific nucleoside (1966-1972)

All MeSH Categories
Chemicals and Drugs Category
Nucleic Acids, Nucleotides, and Nucleosides
Nucleosides
Deoxyribonucleosides
Deoxyadenosines
Cladribine
Dideoxyadenosine
Puromycin Aminonucleoside
Deoxycytidine

- Bromodeoxycytidine
- Zalcitabine +

Deoxyguanosine

Deoxyuridine
- Bromodeoxyuridine
- Floxuridine
- Idoxuridine

Dideoxynucleosides
- Didanosine
- Dideoxyadenosine
- Stavudine
- Zalcitabine +
- Zidovudine

Pentostatin

Thymidine
- Stavudine
- Trifluridine
- Zidovudine

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